DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2015

Ms. Diana DeGregorio
Regulatory Affairs Consultant
SoundCure, Inc.
560 S. Winchester Blvd, Suite 500
San Jose, CA 95128

Re: K150065
Trade/Device Name: SoundCure Serenade Tinnitus Treatment System
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: January 12, 2015
Received: January 13, 2015

Dear Ms. DeGregorio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 150065

Device Name: SoundCure® Serenade®Tinnitus Treatment System

Indications for Use:

The SoundCure® Serenade® Tinnitus Treatment System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older).

This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

Prescription Use X **Or** **Over-The-Counter Use** _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. SUBMITTER

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Date Prepared
January 9, 2015

II. DEVICE

Trade Name:	SoundCure® Serenade® Tinnitus Treatment System
Common Name:	Tinnitus Masker
Classification Name:	Tinnitus Masker
Classification:	21 CFR §874.3400
Product Code:	KLW
Device Class:	Class II

III. PREDICATE

SoundCure, Inc. SoundCure® Serenade® Tinnitus Treatment System (K111293)
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The SoundCure® Serenade® Tinnitus Treatment System (Serenade System) is a personalized sound therapy system designed specifically to evaluate a patient's tinnitus, to create customized audio stimulus, and to deliver and monitor/data log the audio stimulus. The Serenade System is intended to provide relief from the debilitating effects of tinnitus through the use of a hand-held customized digital audio device (Serenade Patient Device) that generates sound therapy/masking. The Serenade System uses modulated tinnitus pitch matched tones (S-Tones) and narrow-band noise centered at the tinnitus frequency and provides broad-band noise. The Serenade System consists of the following components: Serenade Treatment Software, Earphones, Serenade Patient Device as well as the following Accessories: power supply, power cord and USB cable.

The Serenade System with Remote Programming modification is limited to changes to components of the Serenade Treatment Software (Web, PC & addition of Communications Software Component on patient's home computer), modifications to user interface and updates to labeling (Professional, Patient and Patient Remote Connection Quick Start Guide). The Serenade Patient Device and accessories are unchanged.

V. INDICATIONS FOR USE

The Serenade System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older).

This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Serenade System has similar features as compared to the predicate devices in the table below.

Manufacturer	**SoundCure, Inc.**	**SoundCure, Inc.**
Device Name	**SoundCure® Serenade® Tinnitus Treatment System**	**SoundCure® Serenade® Tinnitus Treatment System**
510(k) Number	**K111293**	**Remote Programming Modification**
Indications for Use	The SoundCure™ Serenade™ Tinnitus Treatment System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.	Same
Product Code	KLW Tinnitus Masker, 21CFR874.3400 Class II	Same
Common Name	Tinnitus Masker	Same
Dispensing Professional	Hearing Healthcare Professional	Same
Programming Location	In office	In office or Remotely
Target Population	Adults with Tinnitus	Same
Use Location	May be used anywhere	Same
Physical Description	Handheld device with sounds delivered through earphones	Same
Mechanism of Action	Uses noise that can be configured from broad band to narrow band, and pure tones customized to the patient Stimulus can be amplitude modulated Level of sound can be adjusted by a user volume control Independent volume parameters per ear Stimulus designed to be placed in the background and ignored	Same
Maximum Output Characteristics	Maximum output fixed at 92dB SPL Output Frequency Response:1 kHz to 14 kHz	Same

Manufacturer	**SoundCure, Inc.**	**SoundCure, Inc.**
Device Name	**SoundCure® Serenade® Tinnitus Treatment System**	**SoundCure® Serenade® Tinnitus Treatment System**
510(k) Number	**K111293**	**Remote Programming Modification**
Target Anatomy	Ear	Same
Design Features	Patient Device Sound Generator with frequency shaped sounds Sleep Mode Timer (60 min timer to shut-off when button is pressed) Amplitude modulation Sounds customized to the patient Handheld device with earphones 4 sound programs / tracks (memory for up to 8) Data logging of patient use Individual volume control per ear	Same
Software Architectural Design	Serenade Patient Device (Embedded Software), hearing healthcare professional's computer (PC Software), and SoundCure Server (Web Software)	Serenade Patient Device (Embedded Software), hearing healthcare professional's computer (PC Software), patient's home computer (Communications Software), SoundCure Server (Web Software)
Patient Contact Materials	Silicone earphones	Same
Biocompatible for Intended Use	Yes	Same
Training Course	Specific Training course for hearing healthcare professionals In office support	Specific Training course for hearing healthcare professionals Supplemental Training course (hearing healthcare professionals) for remote programming. In office support
Power	Rechargeable Lithium-Ion (Li-Ion) Battery Serenade System also includes an external power supply (100-250VAC to 5V DC) with power cord for recharging	Same
Meets Applicable IEC60601-1 testing	Yes	Same

The technological characteristics and principals of operation of the Serenade System are substantially equivalent to the named predicate device.

VII. PERFORMANCE DATA

Performance Testing was performed in accordance to Draft Guidance for Industry and FDA Staff: *Class II Special Controls Guidance Document: Tinnitus Masker Devices* dated November 8, 2005. The following performance testing was conducted on the Serenade System to support a determination of substantial equivalence to the predicate device.

- System Output Performance Testing
- Electrical Safety & Electromagnetic Compatibility Testing
- Packaging Validation Testing
- Software Verification and Validation

Results of the non-clinical testing demonstrate that the materials chosen, the manufacturing process, and design of the Serenade System meet the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates the Serenade System is substantially equivalent to the named predicate.

Clinical Performance Testing

A clinical study was conducted to demonstrate that the SoundCure Serenade Tinnitus Treatment System using the remote programming model is substantially equivalent to the Serenade Device using the current programming model (in-office).
The study was a non-significant risk, prospective single site study involving patients with confirmed tinnitus who did not have any previous experience with the Serenade System. Each patient underwent in-office and remote device programming. The purpose of the study was to determine if the patient labeling and remote HHP instructions and process using the patient's PC as an access port for HHP performed matching and device programming, resulted in a successfully programmed device. Differences between parameters obtained from in-person (local) evaluation or remote evaluation should not differ from the known test-retest variability with in-person (local) testing. The results from this study demonstrated that the SoundCure Serenade Tinnitus Treatment System can be successfully programmed remotely without introducing new safety concerns.

VIII. CONCLUSIONS

The Serenade System has been carefully compared to a legally marketed predicate device with respect to intended use/indications for use, technological characteristics, anatomical sites, performance, safety characteristics, and labeling. In addition, non-clinical and clinical testing was conducted to verify and validate the performance of the device and ensure the Serenade System performs as intended and meets the design specifications. The comparison, non-clinical and clinical performance testing

results demonstrate that the device is substantially equivalent to the predicate device for its intended use and does not raise new issues of safety or effectiveness.